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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,661	BERNS ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-127* is/are pending in the application.

4a) Of the above claim(s) *99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-98 and 100-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 2-16-07 has been entered. Claims 89, 90, 93-95, 98, 100, 113, 114, 122, 124 and 126 have been amended. Claims 89-127 are pending. Claims 89-98 and 100-127 are under consideration as drawn to a modified mouse embryonic stem cell.

It should be noted that examiner for the present invention has been changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 89-98 and 100-127 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 2-16-07 necessitates this new ground of rejection.

The phrase "modified cells and unmodified cells..., and/or the progenies thereof" in claims 89 and 90 is vague and renders the claims indefinite. It is unclear what combination of cells is intended. Changing the phrase to "modified cells and unmodified cells, or the progenies thereof or both" would be remedial. Claims 90-95, 112-114, 116-120 and 127 depend from claim 89. Claims 96-98, 100-111, 115 and 121-126 depend from claims 89 or 90.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 89-98 and 100-127 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated modified cells and unmodified cells of an inbred strain of an animal, does not reasonably provide enablement for a composition, which is an organ or tissue, comprising said modified and unmodified cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants' amendment filed 2-16-07 necessitates this new ground of rejection.

The claimed composition can read on an organ or a tissue. The claims encompass an organ or a tissue, either natural or artificial, comprising modified cells and unmodified cells of an inbred strain of an animal. The specification fails to provide adequate guidance and evidence for how to make and use an organ or a tissue comprising modified cells and unmodified cells of an inbred strain of an animal. There is no evidence of record for how to make an artificial organ or tissue and how to introduce a targeting DNA construct into said artificial organ or tissue to produce a mixed population of modified cells and unmodified cells. An organ or a tissue, either natural or artificial, must have a use, however, the specification fails to provide adequate guidance for how to use said organ or a tissue. There is no evidence of record for how to use an organ or a tissue comprising modified cells and unmodified cells of an inbred strain of an animal, therefore, one skilled in the art would not know how to use said organ or tissue.

Further, the claims read on introducing a targeting DNA construct into a plurality of **any unmodified cells** so as to provide a composition comprising modified cells and unmodified cells of **an inbred strain of an animal**. The unmodified cells need not be isolated from an inbred strain of an animal, therefore, when the unmodified cells is not the same as the cells of an inbred strain of an animal, no composition comprising modified cells and unmodified cells of an inbred strain of an animal would be obtained from the method as claimed in claim 89. The specification fails to provide adequate guidance and evidence for how to obtain a composition comprising modified cells and unmodified cells of an inbred strain of an animal by using any type of unmodified cells. Absent such guidance, one skilled in the art would not know how to obtain the claimed composition by using any type of unmodified cells.

For the reasons discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the level of ordinary skill which is high, the working examples provided and scarcity of guidance in the specification, and the unpredictable nature of the art.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 89-98 and 100-127 remain rejected under 35 U.S.C. 102(b) as being anticipated by Capecchi et al. (IDS, C06-1989) and is repeated for the reasons set forth in the preceding Official action mailed 8-22-06. Applicant's arguments filed 2-16-07 have been fully considered but they are not persuasive.

Applicants argue that the invention is directed to an in vitro composition of cells, which is made up of a mixed population of cells that are present in different stages of transformation by a targeting DNA construct, and the flanking sequences of the targeting DNA construct are derived from the same inbred strain of animal as the targeted cells (amendment, p. 10-11). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 8-22-06. Capecchi teaches a method for producing an alteration in a gene of interest by targeting through homologous recombination. Therefore, during the process of said method, the intermediate products of different stages of said method would be produced, i.e. mixed population of modified cells and unmodified cells would be produced during the process. Capecchi teaches "[t]hrough gene targeting, the potential now exists to generate mice of any desired genotype. The experimenter chooses both which gene to mutate and how to mutate it. The criteria for selecting which gene to mutate can be based on knowledge generated within the species or from other species" (e.g. p. 70, left column 3rd paragraph). Capecchi also teaches using available cloned mouse genes or genomic fragment of the mouse genes for gene targeting via homologous recombination (e.g. p. 70, right column, 2nd paragraph). Therefore, it is inherent that one of ordinary skill in the art would use the flanking sequences of the targeting DNA construct derived from the same inbred strain of animal as the targeted cells. Thus, the claims remain anticipated by Capecchi.

7. Claims 89-98 and 100-127 remain rejected under 35 U.S.C. 102(b) as being anticipated by Capecchi et al. (US Patent No. 5,464,764) and is repeated for the reasons set forth in the preceding Official action mailed 8-22-06. Applicant's arguments filed 2-16-07 have been fully considered but they are not persuasive.

Applicants reiterate the same arguments set forth above and the claims remain anticipated by Capecchi for the same reasons set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 89-98 and 100-127 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,653,113. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the claims.

Claims 89-98 and 100-127 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,789,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the claims.

Applicants' indication of submitting a Terminal Disclaimer under 37 C.F.R. 1.321(c) upon indication of allowable subject matter is acknowledged.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/schen

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER